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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/214,851      | 09/09/1999  | EDWARD M SELLERS     | 064658.0129         | 8120             |

21967 7590 07/17/2003

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EXAMINER

DELACROIX MUIRHEI, CYBILLE

ART UNIT PAPER NUMBER

1614

DATE MAILED: 07/17/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

| <b>Office Action Summary</b> | Application N<br>09/214,851            | Applicant(s)<br>SELLERS ET AL. |
|------------------------------|--|--------------------------------|
|                              | Examiner<br>Cybille Delacroix-Muirheid | Art Unit<br>1614               |

**– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 09 January 2003 .

2a)  This action is **FINAL**.                    2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## **Disposition of Claims**

4)  Claim(s) 2,5,6,10-33 and 37-44 is/are pending in the application.  
4a) Of the above claim(s) 5,6,10,14,15,24,31-33 and 37 is/are withdrawn from consideration.

5)  Claim(s) 17-20, 22-23 is/are allowed.

6)  Claim(s) 11, 2, 12, 13, 16, 25-29, 38, 39, 40, 41 -44 is/are rejected.

7)  Claim(s) 21 and 30 is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12)  The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a)  The translation of the foreign language provisional application has been received.

15)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)      4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)      5)  Notice of Informal Patent Application (PTO-152)  
3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s)      6)  Other: \_\_\_\_\_

### **DETAILED ACTION**

1. Claims 11, 12, 13, 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Garnitskij et al., SU 1803032.(based upon an oral translation of the reference).
2. Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Garnitskij, supra in view of Modi et al., 5,653,987.

#### ***Response to Amendment***

The following is responsive to Applicant's amendment received Jan. 9, 2003. Claims 1, 3, 4, 7-9, 34-36 are cancelled. New claims 39-44 are added. Claims 2, 5, 6, 10-33, 37-44 are currently pending. Claims 5, 6, 10, 14, 15, 24, 31-33, 37 are withdrawn from consideration.

The Sequence listing received Jan. 9, 2003 has been received and entered into the application.

The previous claim objections set forth in paragraphs 4-5 of the office action mailed Sep. 9, 2002 **are withdrawn** in view of Applicant's amendment and the remarks contained therein.

The previous claim rejections under 35 USC 112, paragraph 2 and 35 USC 101, set forth in paragraphs 6-10 of the office action mailed Sep. 9, 2002 **are withdrawn** in view of Applicant's amendment and the remarks contained therein.

The previous claim rejection under 35 USC 102(b) over Maenpaa et al. and the previous rejection of claims 7-9, 34-36 under 35 USC 102(b) over Mays et al. **are withdrawn** in view of Applicant's amendment and the remarks contained therein.

However, Applicant's arguments traversing the previous rejection of claims 11, 12, 13, 16 under 35 U.S.C. 102(b) over Garnitskij et al., SU 1803032.(based upon an oral translation of the reference); and the previous rejection of claim 38 under 35 U.S.C. 103(a) over Garnitskij, supra in view of Modi et al., 5,653,987 have been considered but are not found to be persuasive.

Said rejections are maintained essentially for the reasons given previously in the office action mailed Sep. 9, 2003 with the following additional comment:

It is Applicant's position, with respect to the rejection under Garnitskij that the Examiner improperly relied upon the online abstract of the Garnitskij patent instead of a translation of the patent itself. Additionally, Applicant requests the Examiner to obtain a written translation if the rejection is maintained referring to Ex parte Bonfils, 64 USPQ2d 1456, 461 (BPAI 2002). In the absence of such a written translation, the rejection should be withdrawn. Finally, concerning the rejection under 35 USC 103(a), since the Garnitskij is not a proper reference and since Modi et al. does not disclose the information purportedly found in Garnitskij, the rejection should be withdrawn.

Said arguments have been considered but, respectfully, are not found to be persuasive.

The Examiner understands that the use of an abstract, in a rejection, absent a translation of the underlying document is improper. However it is respectfully submitted that the rejection over Garnitskij is proper because the Examiner obtained an oral translation of the Russian patent from a translator in the Translation Branch of STIC. It is this oral translation, which the Examiner relied upon in the rejection set forth at

paragraph 13 (please see the statement in parentheses in paragraph 13 of the office action mailed Sep. 9, 2002). The Examiner did not rely solely on the abstract but relied on the abstract, in part, and the oral translation of the underlying Russian patent. Applicant's attention is respectfully directed to MPEP 901.05(d) where it is provided:

Examiners may consult the translators in the Translation Branch of the Scientific and Technical Information Center (STIC) for oral assistance in translating foreign patents or literature that are possible references for an application being examined. Examiners may also request written translations of pertinent portions of references being considered for citation or already cited in applications. See MPEP § 901.06(a), STIC Services -Translations, and MPEP § 903.03, Availability of Foreign Patents. Examiners may request written translations at any point in the examination process, at the discretion of the individual examiner, but are encouraged to use oral assistance and/or language reference resources as much as possible in the early phases of examination.

Therefore, absent any additional remarks arguing the merits of the 102(b) rejection over Garnitskij and the 103 rejection over Garnitskij and Modi et al, the rejections are maintained for reasons already of record. Please note, the Examiner will honor Applicant's request for a written translation. Yet, since this office action will not be made final, a written translation will not accompany it, but will be forthcoming.

#### ***New Ground(s) of Rejection***

The allowability of claims 25-29 is withdrawn in view of the following new ground of rejection submitted below.

#### ***Claim Objections***

Claims 21 and 43 are objected to because of the following informalities: it is respectfully submitted that claim 21 is awkwardly written. The Examiner suggests the following language which will adequately convey the claimed invention. –A

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pharmaceutical composition for regulating the metabolism of nicotine to cotinine comprising an effective amount of a substance which selectively inhibits CYP2A6 and an effective amount of a substance which inhibits CYP2B6--. In claim 43, line 1, after "capable of", the phrase "regulating inhibition" should be deleted and replaced with -- inhibiting the metabolism-- as this is consistent with the terminology used in the specification at page 19, lines 20-21. Appropriate correction is required. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

Claims 11, 2, 12, 13 16, 25-29, 38, 39, 40, 41 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to a method for treating "a condition requiring regulation of nicotine metabolism to cotinine" by administering to a person in need thereof an effective amount of an inhibitor of CYP2A6 (claim 11) and a substance which inhibits the metabolism of the CYP2A6 inhibitor. The claimed methods of treatment fail to meet the requirement for an adequate written description of the claimed invention as required by 35 USC, 112, paragraph 1. There is insufficient descriptive support for the generic limitation "a condition requiring regulation of nicotine metabolism to cotinine." Furthermore, the claimed methods require treatment of an unspecified disease and no evidence indicates that a treatable disease, other than nicotine use disorders (page 17 of specification), was known to Applicant. In the absence of some understanding of the

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conditions to be treated one of ordinary skill in the art would not have concluded that Applicant was in possession of the claimed methods.

***Claim Rejections – 35 USC §102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 42, 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Garnitskij et al., SU 1803032 (based upon oral translation of the reference).

Garnitskij et al. disclose a method for treating abstinence syndrome in tobacco dependence, the method comprising administering an effective amount of (0.2-0.5 ml) a 1% solution of pilocarpine HCL to the tongue of a human. Please see the abstract submitted herewith.

Claims 42 and 44 are anticipated by Garnitskij et al. because Garnitskij et al. disclose administration of an identical agent, i.e. pilocarpine, to a patient using Applicant's claimed method steps. Accordingly, reduction in nicotine intake as well as a delay in the metabolism of nicotine to cotinine would be inherent.

***Claim Rejection(s) – 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Garnitskij et al. in view of Modi et al., 5,653,987 (already of record).

Garnitskij as applied above.

Garnitskij does not disclose adding an effective amount of a substance which "inhibits" the metabolism of the pilocarpine; however, the Examiner refers to Modi et al., which discloses that combining antioxidants, such as ascorbic acid (vitamin C), with pharmaceutically active agents to prevent degradation of said agents is recognized by those skilled in the art. Please see col. 3, lines 33-36; claim 6. Furthermore, Modi et al.

disclose that protease inhibitors may be added to a pharmaceutical composition to inhibit degradation of the pharmaceutical agent by enzymes. Please see col. 3, lines 46-48.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine pilocarpine with an antioxidant and/or an enzyme inhibitor, with the expectation of avoiding unwanted degradation of pilocarpine, thereby delivering greater amounts of pilocarpine to the patient suffering from tobacco dependence.

Claim 30 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is 703-306-3227. The examiner can normally be reached on Tue-Thur. from 8:30 to 6:00. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is 703-308-7924.

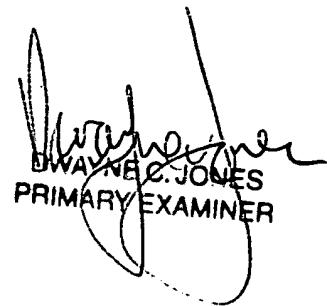
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

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CDM

July 11, 2003

  
DWAYNE C. JONES  
PRIMARY EXAMINER